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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,070	03/06/2001	Yves Delmotte	WM-252.00	4142

7590

06/20/2002

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EXAMINER

WARE, TODD

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/800,070

Applicant(s)

DELMOTTE, YVES

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

DETAILED ACTION

Receipt of declaration and extension of time both filed 9-5-01 and information disclosure statement filed 3-6-01 is acknowledged. Claims 1-36 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5, 8, 9, 10, 15, 26, 29, 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation that the outer diameter is less than 10 mm, and the claim also recites the limitations

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where the diameter is less than 3 mm or is between 100 microns and 2500 microns which are narrower statements of the range/limitation. Also, claim 9 recites the broad recitation that the outer diameter is less than 15 mm, and the claim also recites the limitations where the diameter is less than 10 mm or less than 5 mm or is between 100 microns and 2500 microns which are narrower statements of the range/limitation. Furthermore, claim 10 recites the broad recitation that the tube wall has a thickness between 0.1 mm and 5 mm, and the claim also recites that the wall is between 0.25 mm and 2.5 mm or between 0.5 and 2 mm which are narrower statements of the range/limitation. Claim 5 is also rejected, claiming first density 1.5 times and 5 times the density of the second density. Claim 26 is also accordingly rejected, reciting the broad limitation that a fibrinogen solution has a fibrinogen content of at least 3 mg/ml and narrower ranges of 5 mg/ml and 10 mg/ml. Claim 15 also recites a "range within a range," requiring 5%, 10% and 25%.

Claim 15 recites percentages, but it is unclear what the percentages relate to. Are they for the amount of stretching or the amount "fibrin comprising material?"

Claims 29, 35 and 36 recite either the phrase "preferably" or "advantageously." This renders these claims indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Furthermore, it is unclear when the "advantageous" elements are advantageous and who would decide when they would be advantageous.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 7-10, 12-23, 27, 29-36 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sawamoto et al (5,298,255; hereafter '255).

'255 discloses porous antithrombic stents comprising fibrin formed with fibrinogen and the instant process for their making.

6. Claims 1-4, 7, 9, 12-23, 27-36 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dinh et al (5,510,077; hereafter '077) or Dinh (5,591,227; hereafter '227).

'077 and '227 both disclose porous antithrombic stents comprising fibrin formed with fibrinogen and administration of an active agent with the stent. '077 and '227 also disclose the instant process for their making.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawamoto et al (5,298,255; hereafter '255) or Dinh et al (5,510,077; hereafter '077) or Dinh (5,591,227; hereafter '227).

'255, '077 and '227 all disclose porous antithrombic stents comprising fibrin formed with fibrinogen and the instant process for their making. '077 and '227 also teach administration of an active agent with the stent. The references do not specify the degree of difference between densities, however it is submitted that it would have been obvious to one skilled in the art at the time of the invention to achieve the instant claimed density differences based upon the motivation of providing different thickness, degree of mechanical properties and biostability of the device. Also, it would have been obvious to one skilled in the art at the time of the invention to utilize different diameter stents based upon the blood vessel diameter where the stent is to be used and the provide a wall thickness that would be thick enough to withstand tearing during stretching, but thin enough to allow material to pass through the stent without being too large to place in a blood vessel. Amounts of thrombin would have been obvious to one skilled in the art at the time of the invention with the motivation of providing sufficient thrombin to convert fibrinogen to fibrin.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:00 AM - 4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
June 17, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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